4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1349]

Mikart, LLC, et al.; Withdrawal of Approval of 31 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 31 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040846	Hydrocodone Bitartrate and Acetaminophen Tablets, 325 milligrams (mg); 2.5 mg	Mikart, LLC, 1750 Chattahoochee Ave. NW, Atlanta GA 30318
ANDA 040851	Benzonatate Capsules, 100 mg, 150 mg, and 200 mg	Do.
ANDA 072903	Ibuprofen Tablets, 200 mg	ANI Pharmaceuticals, Inc., 210 Main

Application No.	Drug	Applicant
		St. West, Baudette, MN 56623
ANDA 073519	Tolmetin Sodium Capsules, Equivalent to (EQ) 400 mg base	Do.
ANDA 074267	Guanabenz Acetate Tablets, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074498	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074840	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 074844	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 075212	Ranitidine Hydrochloride (HCl) Tablets, EQ 75 mg base	Do.
ANDA 076030	Flecainide Acetate Tablets, 50 mg, 100 mg, and 150 mg	Do.
ANDA 076086	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg	Do.
ANDA 077426	Ranitidine HCl Tablets, EQ 150 mg base and EQ 300 mg base	Do.
ANDA 077641	Zonisamide Capsules, 25 mg, 50 mg, and 100 mg	Do.
ANDA 077979	Alprazolam Extended Release Tablets, 0.5 mg, 1 mg, 2 mg, and 3 mg	Do.
ANDA 085269	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 085740	Meclizine HCI Tablets, 25 mg	Do.
ANDA 087296	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088164	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088641	Glucamide Tablets, 250 mg	Do.
ANDA 088732	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 088768	Chlorpropamide Tablets, 100 mg	Do.
ANDA 088826	Chlorpropamide Tablets, 250 mg	Do.
ANDA 090572	Cetirizine HCl, Syrup 5 mg/5 milliliters (mL)	Tris Pharma, Inc., 2031 U.S. Hwy. 130, Suite D, Monmouth Junction, NJ 08852
ANDA 090906	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg, and 1 gram (gm)	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd., Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960
ANDA 201944	Potassium Chloride Extended Release Capsules, 8 milliequivalent (mEq) and 10	Tris Pharma, Inc.

Application No.	Drug	Applicant
	mEq	
ANDA 202095	Levetiracetam Extended Release Tablets, 500 mg and 750 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 202246	Levonorgestrel Tablets, 1.5 mg	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960
ANDA 203298	Calcium Acetate Capsules, 667 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 204180	Amiloride HCl Tablets, 5 mg	USpharma Windlas, LLC, 115 Blue Jay Dr., Suite 101, Liberty, MO 64068
ANDA 205442	Linezolid Injection, 600 mg/300 mL (2 mg/mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 205790	Prasugrel Tablets, EQ 5 mg base and EQ 10 mg base	USpharma Windlas, LLC

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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